

How can CombiStats be integrated into a quality-controlled environment?



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Answer:

CombiStats contains several features that support its use in a quality-controlled environment: the different protection levels of the calculation sheets, several options for printing the metadata (e.g. path name, file size) and the unique file identification (hash code) in footnotes. CombiStats offers the required technical control of a compliant system, which, in addition to administrative controls put in place by the user, can satisfy the Title 21 CFR Part 11 requirements. For more information, see section 9 of the [CombiStats User Manual](#).